SIOP Europe
the European Society for Paediatric Oncology

SIOPE News

SIOPE's Community Newsletter
September 2012 Issue 13

# Message from the President and the Office

The moment we have all waited for has arrived: after many years of complaining and many rumours about the timings of release, on 17 July 2012, the European Commission published its draft proposal for a revision of the EU Clinical Trials Directive, in the form of a Regulation. Changing it to a Regulation is important: it ensures that the legislation is immediately enforceable as law in all Member States simultaneously (as opposed to being transposed into national law). Regulations do not provide Member States with the same amount of leeway as a Directive, so we won't see as much disparity in the legislation at national level as we did. At least, we hope not.

What we do want to see is change; change that takes into account the needs of young people with life-threatening diseases like cancer. The SIOPE Board, the ENCCA Project Management Team and the European Clinical Research Council for Paediatric Oncology (ECRC) have called for change countless times: (1) on the role of the sponsor and his/ her obligations, (2) investigational medicinal product (IMP) definitions and "off- label" use as standard practice, (3) risk categorisation of trials and the need for definition of standard treatment and (4) insurance needs. In our preliminary analysis, we are happy to see that many of our concerns are being considered. We now need to consider whether the proposed legislation goes far enough and what the real implications will be, in practice.

The ECRC meeting which is planned for 08 October in SIOP London will be pivotal in defining our position on the draft proposal. All chairs of the clinical trial groups and national societies are warmly welcome and encouraged to attend. It will also strategically set out advocacy plans for the coming months. The SIOPE office will require the help of the entire community to gain the attention of EU and national policymakers. Remember, the proposal could be completely altered by the European Parliament and Member States and we need to make sure we can influence the decision-making process right from the beginning. The co-Chairs of the ECRC, Pam Kearns and Thomas Klingebiel, will do an excellent job I'm sure in coordinating the position of the clinical trial groups on the new Regulation.

In addition we will be organising the SIOPE General Assembly on 07 October in London. All members are welcome to attend and hear about our activities and in particular listen to our plans on a new membership system that can ensure SIOPE truly represents the paediatric oncology community in Europe. Register for the meeting by emailing office@siope.eu. We will also announce the addition of Board member Riccardo Riccardi, who joined the Board again. His commitment to training the next generation of paediatric oncologists is fantastic, and we hope he can once again bring this passion to educate, to SIOPE activities.

I am currently Treasurer and Board Member of ECCO-the European CanCer Organisation, Coordinator of ENCCA, actively involved in the ECRC and although my term as SIOPE President ends shortly, I will remain on the SIOPE Board as Past President for one more year.

I therefore would like to take this opportunity to express my gratitude to all of you who I have met and collaborated with in the past three years in this presidential role. We have achieved so much since late 2009: truly establishing the office in Brussels as the representative for all issues related to paediatric oncology at EU level, setting in motion a campaign to raise awareness of childhood and adolescent cancer by promoting International Childhood Cancer Day on 15 February and organising events several times in the European Parliament.We regulary voice our concerns to regulators and decision-makers in the European Commission as well as national ministries.

Of course, ensuring SIOPE becomes financially stable is also a priority, with action on this taken through participation in key EU-funded projects like ENCCA, PanCare SurFup and the European Partnership for Action Against Cancer (EPAAC) as well as the setup of a new membership system, incorporating national societies or key institutions. Our advancements and successes are always disseminated: check out the SIOPE website, **www.siope.eu** as well as our regular newsletters to keep updated on the latest.

With pleasure, I hand over the presidency of SIOPE to fellow Board member, colleague and friend, Gilles Vassal. I am convinced we have chosen the right man and Gilles will do a great job! The agenda is busy and steering SIOPE through the forthcoming months to ensure our community is represented is essential: Aside from the Clinical Trials Regulation, his interest in improving the EU Paediatric Regulation and innovative drug development, sustainability of ENCCA and ensuring a place for paediatric oncology in the EU research framework programme Horizon 2020 as well as working alongside ECCO and other organisations on 'oncopolicy issues', will be the key drivers to ensuring a successful future for SIOPE in Brussels. His work on sustainability of ENCCA and innovative drug development is essential.

To conclude, I do hope we will continue SIOPE's successful work. I would like to warmly thank the fantastic SIOPE office team in supporting and coordinating our needs, and without whom we would not progress at such a great speed!

**Ruth**

SIOP Europe
the European Society for Paediatric Oncology

## SIOPE: 5 years and many more to come!

In late 2007, six leading paediatric oncologists from across Europe came together to sign into Belgian law the organisation SIOP Europe – the European Society for Paediatric Oncology (SIOPE). Initiated by Prof. Andrea Biondi of Italy, Assoc. Prof. Ruth Ladenstein (AT, and current SIOPE President), Dr. Bruce Morland (UK), Prof. Kathy Pritchard-Jones (UK, SIOPE Past-President), Prof. Riccardo Riccardi (IT) and Prof. Mike Stevens (UK), and under the guidance of Michel Ballieu, the CEO of ECCO- the European CanCer Organisation, the statutes of the organisation were established, with all experts becoming SIOPE's 'Board of Directors'.

Five years on, a lot has happened! Not only is SIOPE a Founding Member of ECCO, but an office has also been established and incorporated into the larger ECCO bureau, with 3 employees (1 full-time, two part-time). Financial and administrative support is also provided by ECCO, through the contracted work of ECCO Finance Manager Thierry Hoppe and Office Administration Coordinator Nicola Pellegrino.

Samira Essiaf, Secretary-General of SIOPE, has been part of the SIOPE office virtually from the beginning, joining Jocelyne Wang in setting up the organisational and administrative structure of the organisation, under the leadership of the then President, Kathy Pritchard-Jones.

Celebrating the last five years, she noted, "Thanks to the excellent leadership of Andrea Biondi, Kathy Pritchard-Jones and Ruth Ladenstein, SIOPE has gone from strength-to-strength. The SIOPE team can proudly say that we have positioned SIOPE firmly on the EU political map as the only pan-European organisation representing childhood and adolescent cancer. It has been a pleasure to be a part of this fantastic organisation and to see it develop so quickly and I have no doubt that even more will be achieved in the coming years, to ensure a brighter future for young people with cancer."

**Milestones of SIOPE to date include:**

- In collaboration with the Communication without Barriers Foundation in Poland and the SIOPE Board, **European Standards of Care for Children with Cancer** were established, with the patronage of former EU Commissioner for Health, Androulla Vassiliou. Consensus on standards was not only established within the paediatric oncology community

SIOPE and SIOP Presidents meeting MEP Glenis Willmott

Patients, professionals and policymakers coming together to create 'Standards of Care for young people with cancer'

ECCO CEO Michel Ballieu was one of the main instigators in the creation of SIOPE

but also with parent and patient groups from across Europe, nurses and other professionals in the childhood cancer multidisciplinary team, as well psycho-oncologists, physiotherapists and legal experts.

• Key instigator in application for the EU-funded project aiming to structure paediatric oncology clinical research in Europe, i.e. **ENCCA– the European Network for Cancer research in Children and Adolescents**. This is a EUR12 million project, incorporating 34 high-level institutions, organisations and IT companies across 11 European countries.

• Creation of the SIOPE Clinical Trials Committee, which later became the **European Clinical Research Council (ECRC) for Paediatric Oncology.** It which aims to link the European clinical trial groups together and addresses common challenges and identifies solutions.

• SIOPE successfully became a partner in the EU-funded Public Health programme project, **EPAAC - the European Partnership for Action Against Cancer**, the only organisation representing a particular age group of patients.

• SIOPE organised two highly successful **'tracks' at the ECCO-led congresses**, the largest of-their-kind in Europe. These excellent congresses, held in Berlin and in Stockholm, successfully profiled SIOPE and positioned multidisciplinary research treatment and care as the best way to help cancer patients both now and in the future.

• SIOPE was appointed with the task of **Work Package Leader for dissemination of the ENCCA** project.

• An awareness-raising campaign is now launched annually, during the month of February to increase understanding amongst EU decision-makers of the significant challenges facing young people with cancer, and those who care for them, culminating in an event in the European Parliament to mark International Childhood Cancer Day on 15 February.

• SIOPE has profiled itself as the voice of paediatric oncology in EU affairs. This has resulted in SIOPE being consulted on various issues at EU policy level, such as developments on paediatric medicines and orphan drugs, multinational clinical trials, child health, secondary prevention, informed consent and other relevant ethical issues related to medical treatment and young people.

• SIOPE has had the opportunity to engage with key stakeholders on different issues and ensure the needs of young people with cancer are considered in policymaking. The SIOPE Board and office has had one-to-one meetings with Members of the European Parliament, key stakeholders in national ministries, regulators and delegates from DG Health and Consumers and DG Research and innovation, in the European Commission.

• SIOPE has organised exhibitions and conferences in the European Parliament in Brussels, and several times the Board and office has been asked to speak and represent the needs of rare cancer patients, and those who care for them.

Ruth Ladenstein, current President of SIOPE, underlined the success of SIOPE. "I am proud of the huge successes of this organisation in such a short time. We still have a lot to do to increase the survival rate of young people with cancer and ensure the best quality-of-life for our brave survivors. However, already the SIOPE community, through the work of the office and the Board, have advanced greatly at EU level and contributed effectively to ensure political decisions that affect our work are evidence-based and patient-centred. We particularly hope our efforts can be seen through our advocacy work of the EU Clinical Trials Regulation in the forthcoming years."

# SIOPE Europe's Community

## Outreach and awareness-building throughout Europe

### EU Projects Updates

## Latest News from ENCCA

### Overview of ENCCA Achievements to Date

The EU-funded, Seventh Framework Programme (FP7) Network of Excellence, ENCCA (European Network for Cancer research in Children and Adolescents **www.encca.eu**) is running for around 18 months now and activities are in full swing. Here we provide an overview of the latest achievements of this dynamic initiative, which aims for the first time to integrate all stakeholders involved in the paediatric oncology field in an effort to facilitate access to therapies and standards of care across Europe, and reduce the existing gaps and limitations.

### News from Parents and Patients (Contributing to Work Packages 2, 4, 13, 14, 15 and 18)

The 3rd European Member meeting (International Confederation of Childhood Cancer Parent Organisations - ICCCPO, **www.icccpo.org**) was held in April, 2012. 42 parents and survivors from 16 different countries gathered at historic Schengen, Luxembourg. Discussions included the various EU projects that ICCCPO is involved in, including ENCCA. Jean-Claude Dupont, who is working with Prof. François Doz on the ENCCA work related to ethical issues, was there to discuss issues such as informed consent and other sensitive issues related to data protection and young people involved in clinical trials.

There was also an appeal by ENCCA Coordinator, Associate Prof. Ruth Ladenstein and SIOPE Communication and Policy Coordinator, Edel Fitzgerald, to the participants for support once the EU Clinical Trials Directive has finally been revised. Professionals and patient/ parent groups need to work closely together and advocate, to be in with a chance of ensuring the mistakes of the past are rectified and the revised legislation goes in the right direction, i.e. ensuring a brighter future for young people with cancer in Europe.

The creation of an advocacy group was discussed, which is a clear deliverable of the ENCCA project. These discussions were further developed in July and we are delighted to announce the names of the **Parent-Patient Advocacy Committee (PPAC)**:

| | | | |
|---|---|---|---|
| ARNOLD Frederic | UNAPECLE | France | http://unapecle.medicalistes.org |
| BASSET Luisa | FEPNC - Federacion Española de padres de Niños con Cáncer | Spain | www.cancerinfantil.org |
| COSTELLOE Jacqueline | Een Häerz fir kriibskrank Kanner | Luxembourg | www.kriibskrankkanner.lu |
| KAMERIĆ Lejla | The heart for the kids with cancer in FBiH | Bosnia and Hercegovina | www.srcezadjecu.ba |

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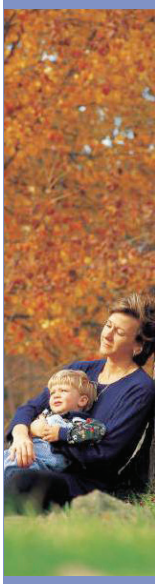
|---|---|---|---|
| KAMERIĆ Neira | The heart for the kids with cancer in FBiH/Cancer Survivor Network | Bosnia and Hercegovina | www.srcezadjecu.ba |
| KARNER Sabine | Österreichische Kinder-Krebs-Hilfe/Survivors Austria | Austria | www.kinderkrebshilfe.at<br>www.survivors.at |
| KIENESBERGER Anita | Österreichische Kinder-Krebs-Hilfe | Austria | www.kinderkrebshilfe.at |
| LACK Peter | Kinderkrebshilfe Schweiz | Switzerland | www.kinderkrebshilfe.ch |
| PFEIFER Renate | Förderkreis für krebskranke Kinder und Jugendliche Bonn e.V. | Germany | www.foerderkreis-bonn.de |
| TSIROU Aimilia | Kyttaro/Greek Survivors Association | Greece | http://floga.org.gr/?page_id=197 |
| **Advisors:**<br>BODE Gerlind | Förderkreis für krebskranke Kinder und Jugendliche Bonn e.V. | Germany | www.kinderkrebsstiftung.de |
| NAAFS-WILSTRA Marianne | VOKK | Netherlands | www.vokk.nl |

## Advancing research on paediatric renal tumours

The Biology-Driven Drug Development Renal Tumours Workshop was a joint initiative by the Università Cattolica del Sacro Cuore (UCSC) and University College London (UCL) and was held on 9-10 June, 2012 in Rome, at the home institution of Prof. Riccardo Riccardi, Policlinico Universitario "A. Gemelli". Riccardi is the leader of **ENCCA Work Package 15** (Education and Training).
This workshop was a highly valuable and interactive outlet for the dissemination of the ENCCA project, with several speakers promoting the project. The organising committee invited parent/patient organisations and experts in the field of paediatric oncology of the 27 EU Member States to this 2-day Conference. Discussions centered on the identification of target markers for existing and future drug development.

## Promoting the importance of long-term follow-up

Prof. Riccardo Haupt, leader of **Work Package 13** (Quality of Survivorship), partnered with IT companies to recently create the first prototype of the Survivorship Passport and the first patient-specific link with a guideline. This English version of the 'passport' is already available and provides a detailed and up-to-date description of the tumour type, treatment, complication during treatment and any other relevant data required for counseling or assessing health needs.
German and Italian versions are soon to follow, while other translations will be made available later when the first prototype will be considered approved. In addition, through close collaboration with Prof. Lars Hjorth and his colleagues from the EU-funded FP7 project **PanCareSurFup**, further surggestions on the follow-up procedure became available. Indeed expertise was not only acquired from European colleagues but also eminent experts and other colleagues from the United States, Canada, New Zealand and Japan provided their suggestions and advice on the format of this electronic 'passport', as reflected



in the guidelines developed for breast cancer screening in survivors of childhood cancer. The challenge they recognise is to translate cancer terminology into language general enough to be comprehensible to other specialists and to patients themselves. ENCCA is working with both professionals and parent and survivor associations to develop ways of streamlining existing databases in order to be more efficient and ensure passports can decrease the administrative burden faced by hospitals and treatment centres.

## Challenges for research on population-based registries

Related to this, leader of **Work Package 11** (Clinical epidemiology and prospective registries for patients on standardised protocols) Prof. Kathy Pritchard-Jones, has been busy attempting to incorporate the needs of the clinicians in routine registry practice, addressing differences in file formats, administrative and confidentiality issues. Further challenges include the variation in national requirements for continuing current trial protocol.

She envisages greater cooperation on advocacy with different groups such as PanCare SurFup to ensure full coverage of cancer registries.

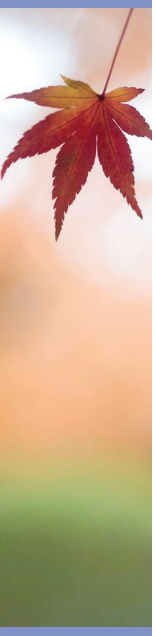
## Largest osteosarcoma study ever performed

Professor Stefan Bielack leader of **Work Package 7** (Integrating clinical trials and tumour biology in bone sarcoma) has made huge advancements by developing the European and American Osteosarcoma Study (EURAMOS-1) which is the largest osteosarcoma study ever performed. Samples obtained from this and other related studies (EuroEwing 99, EURO-B.O.S.S. and other trials) included 2,289 patients from 419 institutions and were registered in the EuroBoNeT virtual Biobank system up until early May 2012.

Access is now available to ENCCA partners and to other experts who wish to contribute cases to the virtual biobank and collaborate and exchange material samples. A first draft for a SOP for entering samples in the biobank has been created and it is anticipated that the SOP will be refined as it is used, taking into account the experience of the users.

## Advancements in neuroblastoma

The Low and Intermediate Risk Neuroblastoma European Study (LINES), part of **Work Package 10,** launched in 2011 with the trial's RDE data base, has been initiated in 14 additional sites, with the other 14 site initiation visits already scheduled for the second half of 2012. Amended guidelines were produced for genomic profile studies of tumours in multicenter multinational studies.



## Ethics: ensuring the patient is at the centre

Led by Prof. Françoise Doz, Leader of **Work Package 18**, the ENCCA Ethics Working Group (Ethical aspects of clinical trials) has undertaken an extensive review of literature and for this purpose liaised closely with ICCCPO and the ENCCA experts promoting teenage and young adult issues in **Work Package 17**. Key discussions that will continue to be analysed include informed consent procedures for research, tissue banking and participation in clinical trials, data protection issues and ethical aspects of fertility preservation.

# Welcome Antonella!

The ENCCA Management Team is delighted to inform you about the recent appointment of Antonella Chiucchiuini, ENCCA Project Manager, based at the Children's Cancer Research Institute (CCRI). Antonella will replace Ivona Brasnjevic, who is leaving at the end of August and will work in close collaboration with ENCCA Coordinator Ruth Ladenstein and with the other members of the Project Management Team to ensure the technical, financial and administrative management of the ENCCA project is completed efficiently.

Antonella comes from Italy. She holds a PhD in Protistology (Biology of unicellular organisms) and a Degree in Biological Science (University of Camerino, Italy).

After working for some years on malaria immunology at the London School of Hygiene and Tropical Medicine she started her carrier as Grant manager/ Project Editor in ALTA, a service provider company specialised in developing and managing scientific research projects. After spending some years in Belgium she moved to Vienna, where she was recruited by CCRI in June.

She has extensive experience as a Grant Manager/Project Editor; former positions included supporting both public and private R&D organisations in the healthcare, life sciences and information technology sector and drafting and managing several projects funded by the EU programmes (FP6&FP7). Antonella took part in contract negotiations and managed scientific and administrative reports writing and project submissions. In addition, she acquired expertise in intellectual property, financial and ethical matters. Moreover she has experience in organising national and international scientific and management meetings.

Antonella's scientific background, management, experience and intercultural competence will be surely valuable for the ENCCA project.

**Welcome on board Antonella!**

# Learn more about TYA issues at SIOP London

The ENCCA Work Package (WP) 17 team (European Network for Teenagers and Young Adults with Cancer, ENTYAC) would like to invite you to attend their symposium, sponsored by Teenage Cancer Trust, taking place at SIOP London this October. This full and varied programme will outline the current work streams of this Work Package, and is structured to stimulate debate and to involve practitioners at all levels, from all European countries, to participate in the work.

The day will highlight the aims and membership of the ENCCA **WP17** in the international context including the socio-economic differences across Europe in healthcare provision. The current work streams to be presented and discussed are:

- Training and education in Teenagers and Young Adults (TYA) with cancer
- Health Services Research
- Survivorship and healthy life styles - fertility preservation
- Clinical Trials for TYA
- TYA Cancer Biology
- Involvement of the patients and public in TYA cancer care research and service development

You are most welcome to attend. If you require any further details please email encca<at>leedsth.nhs.uk (please replace (at) with @)

## SIOP, London, 2012

### ENCCA Symposium

Sponsored by Teenage Cancer Trust
Sunday 7th October 2012, 08.30 - 15.30
Cinema 3, Barbican Centre, London.

Conference organiser, Dr. Dan Stark

# ENCCA promoted at the 7th International Teenage Cancer Trust Conference in June 2012


The ENCCA project (European Network for Cancer Research in Children and Adolescents) was disseminated at the 7th Teenage Cancer Trust International Conference on 25-26 June at the Royal College of Medicine in London, UK.

Giulia Petrarulo, Communication Administrator for SIOPE, attended this unique international conference and disseminated the ENCCA project results and aims (with a special focus on Work Package 17 "Creating a European network for teenagers and young adults with cancer") with a stand in a well-placed spot inside the conference venue.

This biennial conference is the only event in the world solely focusing on the occurrence of cancer in teenagers and young adults. Thanks to a rich and comprehensive programme, professionals from all around the globe and from different disciplines can learn from each other, sharing ideas and approaches, as well as showcasing the latest developments, research and challenges in this developing medical field. Growing in prominence over the years, this year the conference attracted around 230 attendees each day, and it has become the must-attend conference for all professionals working in the field.

# ECRC – European Clinical Research Council

How do you think the EU can improve clinical research ?

## ... Make your voice heard in London in October !

SIOPE has been working closely with the European Clinical Research Council (ECRC) and the ENCCA partners to represent the paediatric oncology community at EU level and outline the position of the paediatric oncology community in terms of the revision of the EU Clinical Trials Directive (2001/20/EC).

The ECRC will focus in particular on three key areas among others in the revised EU Clinical Trials legislation, to ensure the current challenges facing the community are addressed:

- Risk categorisation of trials and need for definition of standard treatment
- Investigational Medicinal Product (IMP) Definitions and "off-label" use as standard practice
- Insurance needs

As the drafted legislation will be reviewed and amended through the EU co-decision legislative procedure (EU Parliament & Council), which could take several years, the ECRC will take the opportunity to use the next ECRC meeting as a platform to discuss how each of the national societies and transnational clinical trial groups could play a key role in advocacy.

We warmly encourage all the Chairs of the national societies and clinical trial groups to attend this and to not miss this opportunity to influence the decision-making process. This next meeting will be taking place at the 44th Congress of the International Society of Paediatric Oncology (SIOP London 2012) on Monday, 08 October 2012.

**More information:**

- Responses to several European Commission consultations (see **website resources**)
- SIOPE-led events in the European Parliament (see website **here** and **here**)
- Several publications (see **website resources**)

- Collaboration with several different groups including the European CanCer Organisation **(www.ecco-org.eu),** Rare Cancers Europe (**www.rarecancers.eu**), EURORDIS - the European Organisation for Rare Diseases (**www.eurordis.org**) and the joint statement with Cancer Research UK (**download here**).

### Important ECRC date to Bookmark

See you at the next ECRC meeting at the SIOP 2012 London Congress on Monday 08 October, 13.30 - 17.30 (Fountain Room, Barbican Centre), after the SIOPE General Assembly.

We hope you can join us!

# Latest News from PanCareSurFup

## Pancare meets in Bucharest

Pancare Childhood and Adolescent Cancer Survivor Care and Follow-up Studies
PanCareSurFup

SIOPE works on dissemination for the EU-funded FP7 project PanCare Childhood and Adolescent Cancer Survivor Care and Follow-up Studies (PanCareSurFup **www.pancaresurfup.eu)**.

PanCareSurFup is a consortium of 16 European institutions from 11 countries that carry out research studies on the late effects of treatment for cancer, coordinated by Dr. Lars Hjorth and based in Lund University, Sweden.

Since SIOPE's last newsletter, PanCareSurFup activities included a successful meeting in Bucharest, Romania, wonderfully organised by The Little People (**www.thelittle-people.org**), who are doing a fantastic job raising awareness of the challenges of paediatric cancer in Romania. The partners of this PanCareSurFup Work Package came together to discuss the progress of the project, as well as its challenges and achievements. The meeting was part of the overall PanCare conference (**www.pancare.eu**), which is a multidisciplinary pan-European network of professionals, survivors and their families that aims to reduce the frequency, severity and impact of late side-effects of the treatment of children and adolescents with cancer.

Currently, the Consortium partners are busy finalizing the 18 month financial report of the project, and many will be attending SIOP London (05-08 October). In the meantime, experts from PanCare and PanCareSurFup will be travelling to Copenhagen in September for the European Cancer Rehabilitation and Survivorship Symposium (ECRS) 2012, to ensure the needs of young cancer survivors are met.

In London, two PanCare-related meetings will take place:

- The **2nd PanCareSurFup General Assembly**, on 04 October, 2012 at Headrooms (located at 1-2 St Johns Path, Clerkenwell, London, EC1M4DD, near the Barbican);
- The **10th PanCare Meeting**, on 08-09 October 2012 in London. On Monday, 08 October, the meeting takes place in the Barbican Centre (Cinema 2) from 14.00 to 17.00. On Tuesday, 09 October, PanCare takes place from 09.00 to 13.00 and from 14.00 to 17.00 in a different venue: the Institute of Child Health in the Leolin Price lecture Theatre, Guilford St., London.

**The PanCareSurFup team looks forward to seeing everybody in London!**

The PanCare and PanCare SurFup team in the Pullman Hotel, Bucharest, Romania, with the excellent organizer, Katie Rizvi of the organisation, 'Little People'

PanCare SurFup Work Package Leader for Dissemination, Dr. Momcilo Jankovic of Italy explains to organizer Katie Rizvi of the organization Little People about the successful bike race in Marostica Italy which raised awareness about the long-term effects of young people with cancer

# ABCD-4-E

## An Advanced Biomedical Collaboration Domain 4 ENCCA

When the ENCCA project was conceived it was clear from the start that a successful 'European Virtual Institute' needs a tailored Information and Communications Technology (ICT) infrastructure. Therefore, Work Package 3, "Establishment of the Virtual Institute Information Portal", aims to create an infrastructure for the specific needs and requirements of the European paediatric oncology research community. **Work Package 3** leader, Gunther Schreier, from the Austrian Institute of Technology (AIT) explains here how the work being started by 3 IT expert groups from across Europe can greatly enhance the work of our community and accelerate cross-fertilisation of expertise.

The aim of this Work Package is to ensure that each participating organisation will have access to the knowledge that accumulates within the ENCCA network. Therefore, a common collaboration and research infrastructure is needed. This can be achieved by establishing an electronic communication and knowledge management portal that provides information both to the general public and to the ENCCA project community in a private domain after authentication. This portal is expected to be fully functional at the end of 2012. Regarding the research domain, a sustainable and standardised ICT infrastructure will be designed, prototyped and evaluated in the course of a pilot application that facilitates the integration of the various research activities within ENCCA.

Three experienced partners from the field of biomedical informatics and eHealth are working on this ambitious goal: the Austrian Institute of Technology (AIT, Austria), the Foundation for Research and Technology Hellas (FORTH, Greece) and CINECA (Italy). This requires an interdisciplinary dialogue to bridge the gap between the demands of the biomedical researchers and the capabilities contemporary ICT technology can offer.

Based on the heterogeneity of the systems and tools that are used today, we have designed a flexible and standardised platform architecture for the ENCCA ICT infrastructure that we call the **Advanced Biomedical Collaboration Domain 4 ENCCA (ABCD-4-E).** According to our vision, in 2014 we will have a blueprint and demonstration system for this ABCD-4-E, capable of empowering the ENCCA community to collaborate as a unified entity.
It also became quite clear that we will need much more resources to establish the ABCD-4-E as a productive system for day-to-day operation than we have available within ENCCA. With the help of the ENCCA partners and further stakeholders (as well as hopefully further sustainable funding from the European Commission, the pharmaceutical/ ehealth industry etc.) we strive to maintain a solid user-friendly structure.

I would like to take this opportunity to invite the SIOPE community to consider working with us in the future: if you work on a research proposal, please contact us to discuss how we can possibly contribute to your project as an ICT supporting partner and - at the same time - make sure that your research project IT infrastructure is designed to be compatible with the upcoming ABCD-4-E. In this way the collaboration network will grow and the European Commision will appreciate this, since it sustainability increases the of your research endeavour substantially and, therefore, also the chances of getting funded!

Günter Schreier
guenter.schreier<at>ait.ac.at
(please replace (at) with @)

**More information:**

**Work Package 3**, Establishment of the Virtual Institute Information Tool.

HEADSMART
be brain tumour aware

INTERNATIONAL CONFEDERATION OF CHILDHOOD CANCER PARENT ORGANIZATIONS

## HeadSmart at ICCCPO conference, SIOP London

HeadSmart is a UK-based campaign aiming to enhance the awareness of symptoms of brain tumours in children and young people (**www.headsmart.org.uk**).

The campaign plans to reduce the time it takes to diagnose children and young people with brain tumours by educating healthcare professionals and the public about the symptoms of brain tumours in children and young people. Reducing the time to diagnose should reduce the long-term disability that many children and young people with a brain tumour currently experience.

ICCCPO - the International Confederation of Childhood Cancer Parent Organisations (**www.icccpo.org**) has invited SIOPE Board Member and brain tumour specialist Prof. David Walker to talk about HeadSmart at SIOP London, on Friday 05 October 2012. This follows the launch of a pan-European campaign to raise awareness of early diagnosis of brain tumours, launched on Rare Disease Day last 28 February. Several brain tumour specialists and parent groups have been interested in starting their own campaign at national level, including groups in Germany, Austria, Spain and Denmark.

We encourage any interested individuals from the SIOP Brain Tumour Group and parent/ patient groups to attend Prof. Walker's lecture, at 10.00 on the Friday of the SIOP London Congress in the Barbican Centre. We look forward to seeing you there!

# Promoting better policies for children with cancer

## Data Protection Regulation

In this newsletter we discuss the controversial proposal tabled by the European Commission this year to protect the personal data of EU citizens. Existing EU rules on data protection were adopted in 1995, when the full potential of the internet had not yet been realised. Private information can range from financial data, such as credit card details, to health conditions or sexual and political orientation. The proposal, if approved by the Member States and the European Parliament, is expected to strengthen citizen's rights and could have a far-reaching impact on the way online data is collected and processed. But what does it mean for patients, and those who care for them? Could the regulation be so strict that it further restricts current public health infrastructures, such as cancer registries? Edel Fitzgerald of the SIOPE office provides an overview of this important legislation.

SIOPE in action: Policy and Communication Coordinator Edel Fitzgerald joins SIOPE members at a meeting with Polish MEP Sidonia Jedrzejewska.

The European Union recognises the protection of personal data as a fundamental right. EU legislation already aims to protect personal data through Directive 95/46/EC, which was adopted in 1995 to protect the fundamental right to data protection and guarantee the free flow of personal data between Member States. In 2008 it was complemented by a Framework Decision (2008/977/JHA) regarding police and judicial cooperation in criminal matters.

Instantaneous communication and major achievements in technology has also brought with it unwelcome controversy, as citizens become increasingly concerned about the usage of their personal data. In relation to health, powerful devices, e-infrastructures and rapid technological advances are ensuring that the medical community can collaborate and accelerate advances across the globe. Indeed, the current Directive has been

interpreted differently across the EU-27 Member States and thus data protection is applied inconsistently.

The complexity and legal uncertainty in relation to international data transfers has been highly cumbersome for several sectors. Thus the European Commission has made an ambitious proposal to tighten harmonisation rules and incorporate current legislation on data protection in a Regulation on General Data Protection, ensuring it would be directly applicable throughout the EU. The new rules if approved, will give citizens "the right to be forgotten".

**How does this affect the health community?** Already Article 8 of the 1995 Directive is particularly restrictive for the health research community, including for epidemiogists, as it prohibits processing of data concerning health, racial or ethnic origin, trade-union membership, religious and philosophical beliefs, political opinions or sex life, aspects which may be relevant for researching the risk of disease. Processing such data is legal only if the data subject has given explicit consent. Across the EU there have been heterogeneous interpretations of the Directive's Article 8 on explicit consent, with some Member States implementing an additional range of data security measures and encryption. In these cases, excessive regulation disabled even the monitoring of the cancer burden, as doctors often stopped reporting cases to the cancer registry, worried that they could lose their licence.

The European Commission hopes the new legislation will create more clarity, coherence and legal certainty for individuals. But harmonisation usually adopts the lowest common denominator: this revision seems to move to restrictive interpretation of the informed consent needed for health, sex and ethnic origin data. **A 'one-size-fits-all' approach can undermine the very aims it seeks to achieve.**

The principle of proportionality needs to be considered in order to allow for different national approaches.

From a public health – and paediatric oncology – point of view, collecting data for medical research and building patients' registries is a priority: however, informed consent is often impossible to obtain when personal data are required for each individual in the population being studied, as it is the case for instance for EU-wide disease prevention research studies.

The 'right to be forgotten', made explicit in Article 17, specifies that data subjects have the right to erase their personal data if there is not legitimate reason to keep them. Children are considered here a vulnerable group, and thus Article 8 of the proposal makes it unlawful to process personal data of a child under the age of thirteen, unless parental consent has been given.

The Regulation does aim to ensure that patients cannot 'delete' personal data that can inflict harm on the public at large, e.g. health risks caused by communicable diseases. Processing sensitive categories of data will be permitted if in the public interest, including in relation to health.

Articles 6 and 9 of the Regulation make provisions for scientific research purposes, aiming to strike a balance between facilitating the security of patient data with the improvement of our understanding of health and disease at individual and population level.

**In relation to biobanks, several surveys indicate the vast majority of Europeans recognise the importance of the practitioners in this field.** At the same time this community needs to guarantee the safety of its data as there is increasing anxiety amongst the general population about data breaches and the use of medical data. It is clear that the EU is aiming to showcase itself as a leader in privacy regulation: thus the biobanking community needs to better communicate its work and its benefits to society as a whole and in modern medicine. Indeed, **information and communication is key**: the milestones achieved to date through the interpretation of research results have been phenomenal, in paediatric oncology and other rare disease areas. This needs to be promoted, especially to truly address the long-term effects facing young people with cancer.

# SIOPE Community Reports and Roundups

## SIOPE warmly welcomes Board Member Riccardo Riccardi

The SIOPE Board and office warmly welcomes back to the SIOPE Board Prof. Riccardo Riccardi of the Catholic University of the Sacred Heart, Rome (Italy). Riccardo already previously held the position on the Board as Chair of the SIOPE Education and Training (ETC) Committee.

Due to his high commitment to educating the future generations of paediatric oncologists he was elected as Work Package Leader of WP15 (Education and Training) in the EU-funded network of excellence, the European Network for Cancer research in Children and Adolescents (ENCCA).

He will now work closely with fellow SIOPE Board member Dragana Janic to promote education and training programmes, particularly in central and eastern European countries.

To date, he has worked on the EU FP7-funded project led by **ECCO** - the European CanCer Organisation, '**Oncovideos**', as well as the highly successful and competitive '**FLIMS**' **Workshop** (ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research). Moreover, Riccardi has been committed to the development of paediatric oncology-focused educational events such as the **ITCC Training Days** and the European School of Oncology (ESO) – SIOPE **Masterclass**.

# SIOPE Education and Training

## Report from ITCC Training Days in association with ENCCA


The annual Innovative Therapies for Children with Cancer (ITCC) training course on "Rational drug development in children with cancer" will take place in Rome, at the Università Cattolica del Sacro Cuore on 12-14 September, this year in association with the European Network for Cancer research in Children and Adolescents (ENCCA). Prof. Riccardo Riccardi, Course Director, provides a brief report on the event and its success.

This educational programme represents a unique opportunity for doctors, nurses and other professionals involved in clinical and translational research, as well as personnel from the pharmaceutical industry, to learn the essentials of early drug development in paediatric oncology from several experts in this highly-specialised field. The course is also open to interested applicants from non-ITCC European institutions.

The Innovative Therapies for Children with Cancer (ITCC) Consortium - which gathers 41 European paediatric oncology departments and 9 European research laboratories - aims to develop novel therapies for the treatment of paediatric and adolescent cancers in cooperation with regulatory bodies, pharmaceutical enterprises, parents and patients.

32 participants from centres in France, Italy, The Netherlands, UK, Greece, Denmark and Spain were registered (19 medical doctors and 13 research nurses and data managers). The course included up-to-date teaching and interactive evaluation of problems encountered in trials conduct. A parallel session was held with a specific programme for research nurses.

**Sessions for all the attendees:**

- ITCC current status and future directions
- ITCC biology: pre-clinical proof-of-concept data packages to support early clinical trial design
- Identification of paediatric oncology specific molecular targets
- Measuring response in paediatric solid tumors
- New approaches to response evaluation of brain tumours
- The role of the research nurse within the early clinical trials team

**Sessions for medical doctors (MD):**

- Statistical aspects in ITCC studies: challenges and solutions
- Evolution of early clinical trials design
- Interactive session for MD: Phase I/II

**Sessions for research nurses and data managers:**

- Early clinical trials: from concept through delivery to completion and interpretation of results
- Interactive session or research nurses: Early clinical trials conduct - roles and responsibilities of research nurses and data managers
- Nurse teamwork in practice: Decision making / involvement of the multidisciplinary team and transition of care post

**Sessions for all the attendees:**

- Reflections and endpoints for the targeted phase I trials
- Interactive session: Ethical issues related to early drug development in children
- Sample logistics: how to get more out of your clinical trial
- Good Clinical Practice

This training course has been taking place for several years now with the involvement of SIOPE and ITCC. The Innovative Therapies for Children with Cancer (ITCC) Consortium - which gathers 41 European Paediatric Oncology Departments and 9 European research laboratories - aims to develop novel therapies for the treatment of paediatric and adolescent cancers in cooperation with regulatory bodies, pharmaceutical enterprises, parents and patients.

This course is expected to take place again next year and provides excellent opportunities for a wide group of stakeholders interested in paediatric oncology drug development.

**More information:**

- **Full report here**
- **ITCC website**
- **Training course programme**
- Contact via e-mail **sara.calmanti<at>igr.fr** (please replace <at> with @)

Riccardo Riccardi, Course Director, in action in Rome Italy at the Training Days

Faculty members Prof. Andy Pearson and Assoc. Prof. Ruth Ladenstein, SIOPE President

SIOPE President-Elect Prof. Gilles Vassal and Dr. Renaud Capdeville, Vice President of Oncology Global Development, Novartis

# 4th ESO-SIOPE Masterclass in Paediatric Oncology

Young paediatric oncologists who wish to improve their skills in clinical management of childhood tumours are participating in the next European School of Oncology (ESO) and SIOPE Masterclass in Paediatric Oncology, which will take place next 24-29 November 2012 in Castel Gandolfo (Rome), Italy. This programme offers a unique learning experience, providing practice-oriented training. The teaching sessions will focus on the application of the most recent research findings to clinical practice.

This Masterclass focuses on state-of-the-art treatment of more common diagnoses (central nervous system tumours, soft tissue and bone sarcoma, neuroblastoma and Wilms' tumour) which are supplemented by sessions dealing with less frequently occurring tumours (for example retinoblastoma, haepatoblastoma). Special lectures will address more general topics such as radiotherapy, clinical trials and new drug development.

Case presentations prepared by all the participants will be discussed between the participants and the experts.

Registrations to the course are now closed. Admittance to the Masterclass was by competitive application, and successful applicants – who have submitted an abstract with proposed presentation of a clinical case relating to one of the main themes of the course (CNS tumours, neuroblastoma, soft-tissue sarcoma, bone tumours, Wilms' tumour) – will have free registration granted.

**More information:**

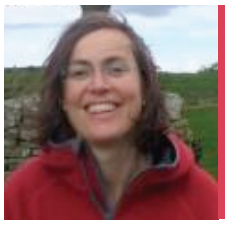
- Event's **brochure**
- Event's **website**
- Contact the organising secretariat at **dknupfer<at>eso.net** (please replace <at> with @)


# Report from FLIMS Fellows

One of SIOPE's objectives is to support and facilitate scientific, medical, professional and educational co-operation across Europe. SIOPE is keen to provide fellowship opportunities to young oncologists in order to attend the hugely popular and highly competitive 'FLIMS' Workshop, Methods in Clinical Research, Switzerland. This workshop allows junior oncologists to learn the essentials of clinical trial design. Working through the night, fellows must put together a protocol in a few days! This unique experience all happens with the help of an excellent faculty of course.

This year we offered two SIOPE fellowships to participate in the 14th Joint ECCO-AACR-EORTC-ESMO intensive workshop, which took place in June. Dr. Britta Vormoor from the Newcastle University, UK and Dr. Susanne Gatz from the Royal Marsden Hospital, UK were selected to avail of these grants; here they have kindly provided some feedback on their experience.

**Britta Vormoor** – United Kingdom
Northern Institute for Cancer Research and Great North Children's Hospital
Newcastle University - Paul O'Gorman Building
Framlington Place
NE2 4HH Newcastle
United Kingdom
Supported by SIOPE



The study that Dr Vormoor has setup and worked on during the 14th Edition of the Flims workshop is an Open label phase I/II of a PARP inhibitor in combination with temozolomide / Irinotecan for adolescent and adult patients with relapsed Ewing's sarcoma. The aim of the study is to determine the safety and PARP-inhibitory doses for treatment with the combination of temozolomide and irinotecan.

I was absolutely thrilled about being selected for this prestigious workshop and felt very honoured when I was informed that I had been the recipient of a SIOPE fellowship grant! I set off to Switzerland in anticipation of a very intense and stimulating experience, and the reality turned out to even surpass my expectations!

The whole course took place at a wonderfully located traditional hotel in Flims, about 1100m above sea level and surrounded by impressive mountains. Still tired from travelling, getting up at 4 am and without any luggage due to delayed flights, I was plunged into an extremely stimulating and intensive learning environment, a mixture of lectures, small protocol development sessions, "meet the expert" seminars and a lot of personal interactions and networking. Very impressive was the number of faculty members who were delivering lectures and coaching the students, thereby passing on their enthusiasm and dedication for clinical trials and cancer research!

The small protocol development sessions are central to the whole experience as the goal of the workshop is to produce an entire protocol proposal just within 5 days! Even during the long evenings when everybody was working on their individual protocols, faculty members, including statisticians, were around to help and give advice on specific questions.

The personal support all students received was truly fantastic.

As a paediatric oncology trainee, I belonged to a minority of just 3 students amongst about 80 other course participants (and a faculty comprising only one paediatric oncologist out of 34 experts), so I initially felt slightly outside my comfort zone with respect to a lot of cancer types, protocols and new drugs, but there is a lot to take on board from the "adult world"!

In summary, the Flims workshop was expertly organised and an outstanding and rewarding experience which I can highly recommend to all paediatric oncologists interested in clinical cancer research.

I am sincerely grateful to SIOPE for supporting me to attend this important course. If you do get selected for Flims, don't forget to bring your swimsuit, you might have a chance to enjoy the dreamlike spa facilities on the last day!

**Susanne Gatz –** United Kingdom
Royal Marsden Hospital
Downs Road
SM2 5PT Sutton Surrey
Supported by SIOPE

The study that Dr Gatz has set up and worked on during the 14th Edition of the Flims workshop is an Open label, multicentre, multinational Phase I/IIa study of the oral Fibroblast Growth Factor Receptor (FGFR) and angiogenesis inhibitor BIBF1120 in paediatric patients with advanced solid tumours. The aim of the study is to evaluate the safety and tolerability of escalating doses of BIBF1120 and to determine the maximum tolerated dose (MTD) and the recommended phase II dose.

Being selected to attend the Flims Workshop as a SIOPE Fellowship grant recipient was a great honour for me. Here I would like to share impressions of my experience of the workshop.

The Flims Workshop provides a unique setting to learn about all aspects of modern clinical cancer research such as (bio) statistics, biomarkers, ethical considerations, legislation and modern clinical/ translational trial designs. This is achieved through a very structured approach which is built around the main aim of each fellow participant: to write a full clinical trial protocol during the time of the workshop.

Four major tools support the protocol writing and learning process: lectures, protocol development group (PDG) sessions, small discussion groups and 'meet-the-expert' sessions (one-to-one discussion). The excellent lectures provided the theoretical background, they covered all aspects and areas, illustrated current 'state-of-the-art', but also raised our awareness of potential pitfalls demonstrated failures in clinical research in the past and outlined the challenges for the future.

The PDG sessions formed the practical basis for transformation of the personal trial proposal into a complete protocol. The proposal and different aspects of the individual trials were discussed in this group and each fellow in the group received detailed critique of their proposals from the faculty in the group but also from the colleagues. It was also very exciting to learn from the protocols of the colleagues and to help each other and to see all our protocols developing.

We were 80 fellows from around the world who met at the "Waldhaus" in Flims with 40 excellent, international experts from the different areas of clinical trial design to succeed in this aim. Amongst us were medical oncologists, surgical oncologists, radiotherapists, radiologists, pharmacologists and also 3 paediatric oncologists. As a paediatric oncologist it was particularly exciting for me to be part of this event since I strongly belief that interacting and networking on the interface between paediatric oncology and all aspects of clinical research in adult oncology is vital for modern paediatric oncology.

Overall this course was "a once-in-a-lifetime" which I would not have wanted to miss. It is a perfect combination of theory and practice. What I learnt and the motivation and excitement I could feel in the whole community of longstanding and young clinical researchers throughout this course, will serve as eternal fuel for all my efforts to help shape modern paediatric oncology including bringing a developed study protocol into clinic.

# SIOPE General Assembly

This year's SIOPE Annual General Assembly takes place at the 44th Congress of the International Society of Paediatric Oncology (London SIOP 2012 Meeting) in the Barbican Centre, London. With topics such as the introduction of the new SIOPE membership system with national paediatric oncology societies, an update on the financial outlook for SIOPE now and in the coming years, as well as information on changes to the statutes of the organisation and handover to new President Prof. Gilles Vassal (Institut Gustave Roussy, France), it is sure to be a very important meeting. Information on SIOPE's position on the Clinical Trials Regulation will be discussed in detail at the ECRC meeting the following day (Monday 8 October).
Book this meeting in your diary now!

SIOPE General Assembly (at the London SIOP 2012 meeting)
**Sunday 7 October 2012**
**12.50 - 13:50**
**Frobisher Auditorium 2**
**Barbican Centre, London**

# Our Community Profiled

How do we balance the 'right to be forgotten' and respect the right to privacy of personal data related to health, with the need to advance science for the benefit of society as a whole? The daily reality for the paediatric oncology community of treating a vulnerable age group throws up very sensitive topics such as the right to privacy, informed consent, the need to access treatment abroad and the transfer and processing of personal data between centres and across borders. As oncology becomes more predictive, personalised, pre-emptive and participatory, and science becomes more globalised, regulators are trying to keep up. Communication between the professional and the patient/ parent at both the local and global level will become even more important. For paediatric oncology, an open discussion incorporating all stakeholders needs to take place to ensure a full understanding of the significant ethical issues involved in treating young people with cancer.

As part of a series of interviews with our multidisciplinary community, we speak to **Prof. François Doz**, a leading French paediatric oncologist based in Institut Curie and his colleague, **Dr. Jean-Claude K. Dupont**, a philosopher and specialist in medical ethics. Prof. Doz and Dr. Dupont work closely together on childhood cancer ethical issues in the EU-funded FP7 project, the European Network for Cancer research in Children and Adolescents (ENCCA). Prof. Doz leads the Work Package (WP)18 , 'Ethical aspects of clinical trials'.

**How did you get involved with ENCCA?**

**FD**: Institut Curie is a project partner within ENCCA, due to its important research and clinical activities (especially inside the paediatric oncology department, headed by Pr. Jean Michon, and the research unit INSERM U830, led by Pr. Olivier Delattre). Institut Curie is, for instance, particularly involved in research on following paediatric cancers: neuroblastoma, medulloblastoma, Ewing tumours, mesenchymal tumours.

**JCKD:** My PhD was in legal philosophy, focusing on the protection of human rights within the Council of Europe. The notion of rights, especially fundamental rights, is entrenched in the medical environment, including in research settings; this is particularly blatant in situations such as paediatric oncology, where minors are concerned. My involvement in ENCCA also stemmed from two different work experiences in the field of health-related ethical issues: as a research assistant at Collège de France (Chair of Philosophy of

Life Sciences) and as a member of the Economic Evaluation and Public Health Committee (CEESP) at the French National Authority for Health (HAS).

**What are the main challenges in your Work Package?**

**FD:** In my view, Work Package (WP) 18 is essential for ENCCA. It is obvious that the major objective of ENCCA is to improve care of children and adolescents with cancer in Europe. It is essential, I think, for all people involved in research, namely professionals together with patients and parents, to be satisfied with the conditions in which research is performed.

Thus, it is the aim of the Ethics Work Package to contribute to secure such a dialogue about the conditions of research. The main challenge concerns the production of consensual guidelines between professionals and parents together with patients. In my view, such a consensus is not to be reached top-down involving only ethical and medical experts; it has to stem from former patients' and parents' views and questions. Consensus does not denote the accommodation of all views and preferences, however. And here is another challenge, namely that professionals feel concerned enough to actively participate in discussing guidelines on research biobanking and on clinical trials which are expected by our WP.

A final challenge relates to taking into account the situation in eastern European countries accurately, which means to involve local representatives from these regions in the dialogue.

**JCKD:** The first challenge is "theoretical". Paediatric cancer research is a minefield for bioethics: there is no simple solution to ethical issues raised in this field, each one requiring an understanding of ample, and sophisticated, literature.

Another challenge is "deliberative": the aim of our WP is definitively NOT to make of paediatric cancer research a battlefield due to unsolved ethical dilemmas... FD already mentioned the need for organising proper deliberation with our partners from the International Confederation of Childhood Cancer Parent Organisations (ICCCPO), as well as with professionals. It is a challenge in itself to make the results of the literature review relevant and understandable, so that it can help these stakeholders to define what is right and the correct way to do things, in their view, provided that it fosters protection without hampering research.

Finally, there is a "logistical" challenge in our WP. Professionals, as well as patients' and parents' representatives, are busy people, with their own priorities and thus have limited time to devote to our WP. Their inputs are vital for us, and it is a constant challenge to make the best use of the rare occasions to address ethical matters with them.

**As a team of a philosopher and paediatric oncologist, how has that been beneficial to the project?**

**FD:** Clearly, I am a paediatrician, not a paediatrician-ethicist. Each medical doctor is almost daily confronted with situations that raise ethical issues. As a consequence, it is natural for medical doctors to develop a careful attitude towards ethical matters, some kind of constant questioning. Medical experience is thus relevant and fruitful for ethical reflection, for it is concrete and practical, but it also has its own limitations, mainly as it reflects a professional point of view. Involvement of a philosopher in ENCCA is thus to ensure an external point of view, but also a matter of complementary expertise in non-medical but other relevant fields, as medicine is part of society.

**JCKD:** As a philosopher, I agreed with FD on the objective to give a clear and descriptive account of existing (thus often colliding) ethical theories and arguments, based on sound and reproducible literature search strategies. Such "descriptive ethics" based on literature review reflects the methods and workflow followed in "full" Health Technologies Assessment (HTA) in Europe, as outlined by the International Network of Agencies for Health Technology Assessment (INAHTA) and endorsed by major health agencies (including Haute Autorité de Santé (HAS) in France). As such, this approach is inconclusive, it is based upon recipients agreeing on appropriate outcomes (be they public decision-makers or stakeholders, depending on the context). That's why deliberation and consultation with parents, patients and professionals is so important for our WP.

**ENCCA is an ambitious project with 34 project partners and many deliverables and milestones: what kinds of challenges do you envisage for the project as a whole?**

**JCKD:** The only challenge I may mention, although I don't have a comprehensive view over the entire project, would be the risk of some "insularity" of each WP. I know that people, especially coordinators, actually work within ENCCA to avoid these negative consequences. But I would like to mention cooperation, which is actually running between WP 17.5 (WP 17: Creating a European network for teenagers and young adults with cancer (ENTYAC)) and our WP, on the topic "Fertility preservation in teenagers and young adults (TYA)". I would be happy to use part of my time in the ENCCA project to make the ethics expertise that has been developed in our WP available to other partners, on their request.

**FD:** ENCCA will succeed if it fosters and popularises paediatric cancer research in Europe. Thanks to SIOPE, paediatric cancer research already has a long and living history in Europe, especially concerning some tumours. And surely, for this history to keep developing, and for ENCCA to succeed, paediatric cancer research has to become everyone's concern in Europe, and not only the concern of all institutions involved in the care of sick children and adolescents.

### Describe your typical working day.

**FD:** My typical working day lasts about 12 hours. It is composed of clinical, research and administrative tasks, for I am also Deputy Director for teaching and research at Institut Curie. I am thus involved in a variety of professional activities, but it is important for me to stress that I still have active medical practice, receiving patients and families in consultation every week, visiting patients when they are hospitalised, and attending multidisciplinary staff meetings. My domains of particular expertise are paediatric neuro-oncology, retinoblastoma and new drugs.

**JCKD:** Rather than describing a typical day, I will describe my typical workflow in this project. Some days are dedicated to "technical" activities such as defining and testing literature search algorithms, drawing comprehensive mind-maps of colliding arguments and theories, preparing workshops or presentations. Other days are dedicated to scrutinising literature, mainly journal articles, and read monographs. And naturally, another sequence consists of drafting and amending expected deliverables! I learned from experience that I am more efficient while being "sequential" in my work; but this is also tied to the methodology explained above: it is natural to identify a literature sample, to go through it and then to analyse the results, isn't it? There is also a significant amount of working days dedicated to travelling to meetings and workshops.

### What do you love most about your job?

**FD:** Certainly its variety, from clinical research to even philosophical research nowadays! I do really carry out multi-faceted activities, including very practical aspects related to the organisation of research within an institution like Institut Curie. However, nothing is more important to me than the personal relationship with the children here and their parents.

**JCKD:** The prospect for philosophy to be operational, thus "useful" to some extent. I do have a deep respect for academic work in philosophy, including moral philosophy and meta-ethics, but I do think that philosophy – along with social and legal sciences – also contributes to reduce uncertainty, clarify disagreements and help decision-making, be it individual or collective.

### What would you like to see happen next withing the ENCCA project?

**JCKD:** In addition to the core objectives pursued by ENCCA, I would reply: "a sustainable network of expertise in ethical issues in paediatric oncology environment". A first step towards this objective is the constitution of an Ethical Advisory Group within our WP. This group is led by Pr. Anne Fagot-Largeault, from Collège de France and the French Academy of Sciences. I think it could be helpful and efficient for professionals and parents'/patients' representatives to have within reach a stable network of people aware of the needs, challenges and hurdles of paediatric cancer research, collectively competent in all dimensions of ethics.

**FD:** "Sustainability" is definitely a keyword for ENCCA, indeed. It means that, what will be promoted and realised during this project, can become established and stable over the years. This is essential for facilitating and developing research, in the view of always curing more and more children while reducing relapses and late effects. Regarding our ethics WP, I would like the guidelines, which are expected to be created during ENCCA, to create a dynamic and establish a discussion on these issues. Indeed, the social and intellectual environment will keep on moving, creating a need for continued reflection and dialogue.

### Which famous person inspires you? Why?

FD: I won't mention a person but a book of Stefan Zweig, which I am currently reading, given to me by my colleague Martin Brenesch from Wien while he stayed at our institute for a few weeks. Zweig describes the inter-war years and I do appreciate, in particular, the subtle and careful way he analyses the social and political context, although he was himself deeply and personally involved. In general, I am opposed to one-sided and simplistic viewpoints.

**JCKD:** Rosa L. Parks. Because she refused to give up her seat to a white man in a bus, a whole social order was turned upside down, namely the "separate but equal" doctrine which was in force in the US at that time. Her resoluteness alone, together with the unity and mobilisation of the black minority, made such a snow-ball effect possible. It also shows that there is no "substantial" definition of our fundamental rights; dissent, argument and dispute are positive values as far as appropriate deliberative institutions exist, for only disagreement has the potential for changing our minds and practices.

### How do you relax? Any hobbies?

**JCKD:** I play the trumpet and the flugelhorn in a band named "OVNI tender". I also love hiking and mountain-biking, but as I live in Paris, it is often some kind of "thought experiment", unfortunately.
**FD:** I have an interest in cultural life and sport. To put it in a nutshell!

### Describe one of your proudest moments/ an achievement you are particularly proud of.

**FD:** In my professional life, I do particularly value fostering the development of my younger colleagues. It is a valuable achievement, and it is essential for paediatric oncology, to see young colleagues succeed in developing top care and research abilities. It is important for them personally, for medical staff and, most importantly, for patients and families.

**JCKD:** The academic defence of my PhD took place on 5th December. 2009. The building overlooked the city and, as I was coming out, huge fireworks illuminated the night. I know it was a holy day celebrating Saint Nicholas, but I could not help but feel proud!

# Special Features

## The Impact of the Financial Crisis

Undoubtedly the economic downturn in Europe and globally has had severe repercussions across all national health systems, as hospitals and research institutes scramble to secure funding while the finance ministers attempt to cut the ever-burgeoning health budgets. Indeed, healthcare represents the biggest expense to Europe's national budgets after pensions, and will be the fastest growing item of government expenditure in the coming decades due to the ageing population. Europe's decision-makers are facing tough choices. What affect has this had on the paediatric oncology community and young cancer patients?

Earlier this year, SIOPE contacted key opinion-leaders from Greece and Ireland, Dr. Helen V. Kosmidis and Dr. Michael Capra. Greece and Ireland are two EU Member States that have faced huge financial challenges. To put this crisis into context: the healthcare budget in Greece has been cut by around €1.9 billion since 2009, and officials say as much as €700 million will have to be saved in healthcare in 2012. In Ireland, €868 million is due to be cut from it's health spending in 2012.

### The Greek Experience
**Helen V. Kosmidis**

*Paediatric Haematologist – Oncologist, Coordinating Director of the Oncology department of Children's Hospital of Athens, "P&A Kyriakou"*

**What have been the main consequences for you and your colleagues due to the austerity measures currently being taken?**

**HK:** Austerity measures have influenced firstly our salary and our security benefits. Pensions have decreased and are expected to further decrease in the year(s) to come. The age of retirement has increased but our colleagues retire before the due age as they anticipate the above mentioned decreased pension.

**What is the feeling amongst the paediatric oncology community about the financial crisis? Do you see light at the end of the tunnel?**

**HK:** The feeling amongst the paediatric oncology community reflects the outlook of the Greek people generally. There is no optimism and even the more optimistic amongst us feel we have a very long and difficult way to go.

**Are financial cuts in your hospital/clinic having an impact on childhood and adolescent cancer screening programmes, diagnosis, treatment, access to cancer drugs and medical services?**

**Is your hospital/clinic experiencing cuts in hospital budgets, understaffing, and shortages of medical supplies? Do you think there is a decline in admissions to private hospitals?**

**HK:** Our hospital is one of the two largest paediatric facilities in Greece. It is part of the national health system and one of the paediatric clinics of Athens University. Paediatric oncology is not really practiced in private hospitals. Although we experience serious cuts in the hospital's budget, in general, diagnosis, treatment access to chemotherapeutic agents and other services are so far not affected and diagnosis and treatment of children and adolescents with cancer are provided without major problems and difficulties.

However: Understaffing is a serious problem. Doctors and nursing personnel are not easily hired and most of the times retired physicians are not substituted. There is also a shortage of medical supplies (although not so far influencing the care of the patients).

**Do you think the pharmaceutical industry is under increasing pressure, as governments seek to drive down the price of medicines, and sometimes leave the bills unpaid? Is your government simply focusing on acquiring medicines at the lowest possible cost?**

**HK:** The Greek Ministry of Health has introduced generic drugs that are less expensive. Unpaid bills to pharmaceutical companies are common and drugs arrive with major delays and after bills are paid. However, usually the hospital's pharmacy maintains an appropriate small stock of commonly used cytostatics and antibiotics.

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**Do you think that care for childhood and adolescent cancer patients is being adversely affected by the cuts in healthcare?**

**HK:** So far care is provided without major problems, protocols are followed as in the past, supportive care and blood products are used as in the past but we are very anxious about future.

**What could your government do improve to address these challenges?**

**HK:** The Greek government needs to recognize that health and education are the main cornerstones for development and other areas need to be cut, but to pinpoint which areas is of course a challenge.

**How can your colleagues in other European countries help?**

**HK:** Junior paediatric oncologists should be given the opportunity to avail of lower registration rates for key educational meetings; the Hellenic Society of Pediatric Hematology-Oncology (HeSPHO) and its members could have free access to appropriate journals etc. which would be very beneficial.

## The Irish Experience
### Dr. Michael Capra

*Our Lady's Children's Hospital, Crumlin, Dublin*

**What have been the main consequences for you and your colleagues due to the austerity measures currently being taken?**

**MC:** Salary reduction, introduction of new 'stealth' taxes (universal social charge, pension levy).
The age of retirement is extended to 65 years with no possibility of early retirement before this.

**What is the feeling amongst the paediatric oncology community about the financial crisis? Do you see light at the end of the tunnel?**

**MC:** The financial crisis is here to stay for many years at least, with no obvious light at the end of the tunnel. Morale in the multidisciplinary paediatric oncology community is very low. The workload is increasing dramatically, together with the intensity of treatment now available being much more than historical treatment. The gap between the increasing workload and decreasing resources is widening.

**Are financial cuts in your hospital/clinic having an impact on childhood and adolescent cancer screening programmes, diagnosis, treatment, access to cancer drugs and medical services?**

**MC:** Yes, the financial cuts are affecting the delivery of service now.

These cuts include:

- A moratorium on staff recruitment and not replacing staff who leave or who are on maternity leave (initially for non-frontline clinical staff but now includes frontline services including nursing staff) – thereby putting excessive pressure on remaining staff to provide the service under very challenging circumstances. In order to maintain a service in the face of diminishing nursing and administrative support staff, consultants are now forced to perform a significant amount of administrative and patient coordination tasks themselves, thereby putting further pressure on their time, increasing the potential of clinical mistakes and therefore increasing the potential risk to their patients.
- Closing beds thereby reducing the number of patients at any one time in the hospital – this has a knock-on effect in paediatric oncology in that elective admissions for chemotherapy, including haematopoietic stem cell transplantation, are sometimes delayed due to no available beds and/or no available nursing staff.
- Limiting the available time to access diagnostic imaging modalities, due to staff shortages t.g. the one and only MRI scanner in our hospital is accessible for only 40 out of the available 168 hours in a week.
- Access to medication – this is becoming more challenging. Accessing medication even for standard collaborative trials is now problematical in some cases.

As a result of the "globalisation" of health care, facilitated by the ease of internet communication, coupled with patients and/or parents lack of confidence in a health service that is becoming more restricted, the demand for second international medical opinions has significantly increased. The tendency is for patients/parents to believe that treatment is better elsewhere, particularly in the USA. Thus there is a need to build a trusting patient/parent and doctor relationship. We need to acknowledge differences in treatment options worldwide,

discuss the advantages and disadvantages of 'medical tourism' particularly in our cohort of patients, the gathering of clinical material necessary for a comprehensive second opinion, and importantly, to empower parents at times to differentiate possible exploitative rather than realistic claims from international centres.

**Do you think that care for childhood and adolescent cancer patients is being adversely affected by the cuts in healthcare?**

**MC:** Yes, I believe the financial cuts are now starting to impact the care of our patients.

**What could your government do improve to address these challenges?**

**MC:** We all acknowledge the extraor-dinary financial challenges that we are up against at personal, local, national and international levels and therefore this is not an easy question to answer. I believe governments require certain priorities in their austerity measures, with one of these priorities to be the protection of resources available to children especially those with rare, life-threatening but potentially curable diseases.

**How can your colleagues in other European countries help? This is a difficult question.**

**MC:** Some potential suggestions include:

- Consider pan-European legislation that can facilitate the acquisition, delivery and accessibility of proton radiotherapy across Europe.

This is a very limited resource, only currently available in Switzerland (1 centre) and to a lesser extent in Paris (1 centre). The future of radiotherapy is more than likely going to be down the proton radiotherapy route rather than currently available conventional radiotherapy, as proton radiotherapy will potentially cause less long-term side effects in the future. For children this is a significant issue. Currently there is a demand that is not met by resources and I anticipate that individual countries do not have the financial option of considering such treatment: But within a European context, this may be more possible and equitable in the future. Currently we have to send patients to Switzerland which can cost around € 30K to 40K, and if they do not have available slots, we have to seek support in the USA (at a considerably greater cost ranging from $150 to 400K).

- Increase the number of open international/ pan-European clinical trials. They offer the best known standard of care, giving consistency to treatment, confidence to patients/ parents and staff of uniformity and thereby decreasing the perception that treatment is "better" elsewhere.

Imagine for Margo
Children without CANCER

Innovative Therapies for Children with Cancer
ITCC
European Consortium

enfants sans Cancer
course solidaire
enfantssanscancer.com

## Imagine for Margo organises « Enfants sans Cancer » event

Innovative Therapies for Children with Cancer (ITCC), together with the French-based charity 'Imagine for Margo' will organise a race to raise funds that can help kick-start an innovative study to help children with low grade gliomas. Taking place in the splendid park Bois de Boulogne in Paris, France, the run is 9 km long (or, alternatively, 5 km long): everyone, alone or with a team, can walk or run in a friendly atmosphere with lots of entertainment including music and prizes, and all for a good cause

This event has been created by 'Imagine for Margo', in partnership with ITCC. Imagine for Margo is a non-profit association which organises events and carries out advocacy and fundraising initiatives to enhance European research on innovative and more effective treatments for children with cancer, as well as providing support to affected families and contributing to the well-being of hospitalised children.

You can register for this event on **www.enfantssanscancer.com** (click on "s'inscrire pour la course") or create a donation page (English version available): anyone can enter the race by raising at least 200 € for the project.

If successful, it is hoped that this will be the first of many such races to raise funds for childhood cancer research.

**More information:**

ITCC Consortium event page
http://imagineformargo.org
www.enfantssanscancer.com

# News bites

## Don't forget the SIOPE General Assembly

See you at **SIOPE's General Assembly i**n SIOP London (Barbican Centre), 05-08 October 2012!! Our General Assembly will be held during the SIOP London conference so we hope you can join us. SIOPE's Annual General Assembly and Reception takes place on Sunday 07 October 2012 between 12.50 and 13.50. All Members are warmly welcome!

## New Clinical Trials Legislation: Have your say!

A revision to the highly controversial EU **Clinical Trials Directive** has been proposed by the European Commission. It is now in the form of a 'Regulation', which means that the legislation becomes immediately enforceable in Member States - different to a Directive, which has to be transposed into national law. **SIOPE's position on the new legislation will be assessed on Monday, 08 October in London at the ECRC meeting!**

To view the proposed legislation, which will now be reviewed and assessed by national ministries and Members of the European Parliament, click HERE.

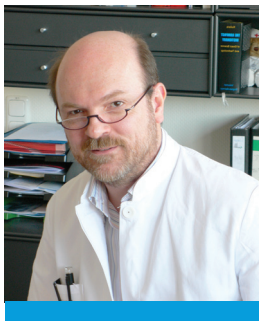
To view SIOPE's advocacy work on amendments to the EU Clinical Trials Directive, click HERE.

## SIOPE on Social Media

SIOPE is actively present on LinkedIn and Twitter. **LinkedIn** is an excellent tool to raise awareness amongst professionals and encourage engagement on SIOPE's initiatives, as well as to track developments of related groups. **Twitter** is a real-time information network that connects people to the latest stories, opinions and news: with just a tweet, millions of people can learn about and show their support for positive initiatives that might have otherwise gone unnoticed. Both LinkedIn and Twitter have a phenomenal influence on our society: Twitter is currently adding 300,000 users a day, while LinkedIn members have reached 147 million this year! This is why social media are an optimal channel to make the voice of the paediatric oncology community finally heard.

# Treasurer's Corner

After some concerns last year about the future financial situation of SIOPE, the budget appears to be much more consolidated due largely to the very successful ECCO-ESMO-ESTRO meeting in Stockholm in 2011. As a Founding Member of ECCO, CEO Michel Ballieu informed the SIOPE President Ruth Ladenstein and myself about the success of the conference and its impact on ECCO Founding Members in July, 2012. Compared to previous congresses, this year SIOPE and its fellow ECCO Founding Members have benefitted greatly, thanks to the excellent efforts of the organisers, but also thanks to the specific support of ECCO's CEO Michel Balllieu.



In addition, the SIOPE President Ruth Ladenstein and the SIOPE office have been very successful in encouraging national societies to join SIOPE and provide their members with the opportunity to join SIOPE through national society membership. The majority of societies have responded positively at this stage. Accordingly, the Statutes of SIOPE were updated in order to establish clear mechanisms of participation for our new membership. These revised statutes will be presented for approval by SIOPE members at the General Assembly, London.

Hopefully you already have been informed about the importance of joining SIOPE at your annual meeting and/ or by the Chair of your group/ society. I hope you will fully support this cause, the details on membership and voting rights of which will elaborated on, at SIOPE's General Assembly in London on 07 October, 12.50-13.50. See you there!

**Martin Schrappe**

# Upcoming Events

JOINT EFGCP / DIA / EMA CONFERENCE ON DEVELOPMENT OF PAEDIATRIC MEDICINES: FROM LEARNING TO ADAPTING
26-27 September 2012, London, United Kingdom
More details

44TH CONGRESS OF THE INTERNATIONAL SOCIETY OF PAEDIATRIC CANCER (SIOP)
05 - 08 October 2012, London, United Kingdom
click here for More details

SIOPE GENERAL ASSEMBLY
08 October 2012, SIOPE General Assembly, London, UK
click here for More details

EUROPEAN CLINICAL RESEARCH COUNCIL (ECRC) MEETING
08 October 2012, SIOPE General Assembly, London, UK
click here for More details

6TH INTERNATIONAL SYMPOSIUM ON CHILDHOOD MYELODYSPLASTIC SYNDROME AND BONE MARROW FAILURE SYDROMES IN CHILDHOOD (EWOG MDS)
07 - 09 October 2012, Prague, Czech Republic
click here for More details

ITCC GENERAL MEETING
18 -19 October 2012, Paris, France
click here for More details

8TH NATIONAL CANCER RESEARCH INSTITUTE CANCER CONFERENCE
4-7 November 2012, Liverpool, UK
click here for More details

4TH ESO-SIOP EUROPE MASTERCLASS IN PAEDIATRIC ONCOLOGY
24 - 29 November 2012, Castel Gandolfo (Rome), Italy
click here for More details

1ST EUROPEAN CONGRESS ON PAEDIATRIC PALLIATIVE CARE
28 - 30 November 2012, Rome, Italy
click here for More details

EFGCP ANNUAL CONFERENCE 2013 – 20TH ANNIVERSARY
29-30 January 2013, Brussels, Belgium
click here for More details

EORTC-EANO-ESMO CONFERENCE 2013
22-23 March 2013, Prague, Czech Republic
click here for More details

2ND ESTRO FORUM 2013
19-23 April 2013, Geneva, Switzerland
click here for More details

24TH ANNUAL MEETING OF THE INTERNATIONAL BFM STUDY GROUP
17 -19 May 2013, Kiel, Germany
click here for More details

4TH ICCCPO EUROPE MEETING
24-26 May 2013, Basel, Switzerland
click here for More details

ASCO ANNUAL MEETING
31 May – 4 June 2013, Chicago, USA
click here for More details

# About US

SIOP Europe
the European Society for Paediatric Oncology

Working to ensure the best possible care and outcomes for all children and young people with cancer in Europe

**www.siope.eu**

Working to ensure the best possible care and outcomes for all children and young people with cancer in Europe SIOPE focuses on making a difference and improving the quality of life of young cancer patients.

To do this, SIOPE supports the pooling of initiatives and expertise of multidisciplinary stakeholders in paediatric oncology, building their common experience into a positive force and creating a brighter future for young people with cancer.

**Support** and facilitate professional, medical, scientific and educational co-operation and training across Europe

**Integrate** patients and parents and bridge the gap between family groups, professionals and policymakers in Europe

**Optimise** access to information and promote multi-centre and multinational clinical trials, forming a common platform for best practice guidelines in clinical research

**Promote** better policies for children with cancer and raise awareness of the numerous challenges faced by paediatric oncology professionals to EU policymakers

**Elevate standards** for training and care in paediatric oncology and develop European guidelines

**To view previous newsletters go to www.siope.eu**

To find out how you can help, please contact us at office[at]siope.eu (please replace [at] with @).

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**http://linkd.in/QdoGAL**


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